

from the:
INTERNATIONAL SEARCHING AUTHORITY

to:

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PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

Applicant's or agent's file reference 511811 NJC		Date of mailing (day/month/year) 23 DEC 2004
		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/NZ2004/000246	International filing date (day/month/year) 8 October 2004	Priority date (day/month/year) 8 October 2003
International Patent Classification (IPC) or both national classification and IPC Int. Cl. ⁷ A61M 16/06		
Applicant FISHER & PAYKEL HEALTHCARE LIMITED et al		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Box No. I Basis of the opinion

With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 6, 15, 21-23, 27, 31, 32, 34, 35	YES
	Claims 1, 2, 3, 4, 7-10, 13, 14, 16, 18-20, 24, 26, 28-30, 33	NO
Inventive step (IS)	Claims -	YES
	Claims 1-35	NO
Industrial applicability (IA)	Claims 1-35	YES
	Claims -	NO

2. Citations and explanations:

The following documents have been identified in the International Search report as possible citations for use in an inventive step or novelty argument:

D1 WO 1998048878 (MORGENSTERN et al.)
D2 WO 1998024499 (RESMED LIMITED)
D3 WO 1982003548 (SOMED PTY LTD)
D4 US 2002/0026934 (LITHGOW et al.)
D5 AU 200071882 (McCUDDEN)
D6 EP 1293227 (FISHER & PAYKEL)
D7 EP 1020201 (RESMED LIMITED)
D8 US 5,662,101 (RESPIRONICS INC.)

The present application is for an apparatus designed to overcome problems with current problems with respiratory masks with comfort when worn for long periods of time. The invention here appears to be in the many forms of adjustment and in the support for the conduit on the headgear which allows movement of the conduit without necessarily disrupting the seal of the mask against the face.

Document D1 discloses a mask and support system for a CPAP application, comprising a forehead and back of the head rests, support for the mask and the conduit on the head gear and a transverse adjustment of the connection between the headgear and the conduit. It is submitted that the claims 1, 2, 4, 7-9, 13, 14, 16, 24, 26, 28, 33 have been anticipated by this document. Claims 3, 6, 10, 11, 12, 15, 17-23, 25, 27, 29-32, 34, 35 have not necessarily been anticipated by the document but do not involve an inventive step over what is disclosed.

Document D2 discloses another mask and harness assembly, again for use in CPAP treatment. It discloses a simple harness with a traverse strap across the head, a rest for the back of the head and a support for the conduit. It is submitted that the claims 1, 2, 3, 7-9, 13 18-20, 26, 30, 33 have been anticipated by this document. Claims 3, 4, 10, 11, 12, 14, 15, 16, 17, 21-25, 27-29, 31, 32, 34, 35 have not necessarily been anticipated by the document but do not involve an inventive step over what is disclosed.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Document D3: device for treating snoring sickness that has two conduits coming out from the mask interface, and each of these is supported by a traverse strap that extends around the head. It is submitted that the following claims 1, 4, 7, 8, 24 have been anticipated by this document. Claims 2, 3, 6, 9, 10-23, 25-35 have not necessarily been anticipated by the document but do not involve an inventive step over what is disclosed.

Document D4 is a system of supports that relieves pressure on the nose by providing a forehead support. It has two parallel straps, providing support at the interface level and across the forehead to support the conduit. It is submitted that the claims 1, 2, 3, 7, 8, 9, 10, 13, 19, 20, 26 have been anticipated by this document. Claims 4, 6, 11-18, 21-25, 27-35 have not necessarily been anticipated by the document but do not involve an inventive step over what is disclosed.

Document D5 is an Australian application that demonstrates support for the facial mask using the head gear and a cap that is worn on the back of the head of the user. The support system also has a chin strap. It is submitted that the following claims 1, 7, 13, 29, have been anticipated by this document. Claims 2-4, 8-12, 14-28, 30-35 have not necessarily been anticipated by the document but do not involve an inventive step over what is disclosed.

Document D6 defines the general state of the art but is not directly related as there is no support for the conduit using the headgear, although there is a mask interface and adjustable support for the interface. The invention here lies in the quick release mechanism where a cord immediately opens up the back of the headgear.

Document D7 defines the general state of the art but is not directly related as again there is no indication of additional support for the conduit through use of the headgear. They disclose a sliding connector for the mask so that the headgear can move without effecting the seal of the mask. The different elasticities of certain portions of the strap enable the users head to be tilted without effecting the position of the mask.

Document D8 defines the general state of the art but is not directly related as there is no support for the conduit. There is support for the mask from both the transverse straps, one sitting at the mouth level and one across the forehead, and from the cap that sits on the back of the head.

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Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
P, X US 2004/0035427	26 February 2004	19 August 2003	20 August 2002
P, X WO 2004030736	15 April 2004	15 September 2003	2 October 2002
P, A US 2004/0035428	26 February 2004	22 August 2003	14 June 2001
P, A US 2004/0083534	6 May 2004	28 March 2003	30 October 2002

US 2004/0035427 discloses a support for a face mask where conduit is support by a cap which sits on the head, which is adjustable.

WO 2004/030736 discloses support for a face mask where the conduit and face mask are supported by the headgear. There is also a release mechanism described which allows quick removal of the structure.

US 2004/0035428 discloses a sliding support which moves independently of the mask allowing the mask seal to remain unbroken.

US 2004/0083534 discloses headgear support comprises a chin strap and a strap across the forehead, both of which are adjustable.

2. Non-written disclosures (Rules 43bis.1 and 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 5 is ambiguous in that it compares the flexibility of one conduit to itself. It is not certain from this drafting which conduit is meant to be more flexible. Thus this claim is not searchable.